

Food and Drug Administration, HHS

§ 107.210

Nutrients	Unit of measurement	Minimum level	Maximum level
Vitamin E	do	0.7
Vitamin K	Micrograms	4
Thiamine (vitamin B ₁)	do	40
Riboflavin (vitamin B ₂)	do	60
Vitamin B ₆	do	35
Vitamin B ₁₂	do	0.15
Niacin ¹	do	250
Folic acid (folacin)	do	4
Pantothenic acid	do	300
Biotin ²	do	1.5
Vitamin C (ascorbic acid)	Milligrams	8
Choline ²	do	7
Inositol ²	do	4

Minerals			
Calcium	do	60
Phosphorus	do	30
Magnesium	do	6
Iron	do	0.15	3.0
Zinc	do	0.5
Manganese	Micrograms	5
Copper	Micrograms	60
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

¹The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide).

²Required only for non-milk-based infant formulas.

In addition to the specifications established in the table in this paragraph for vitamins and minerals, the following also apply:

(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phyloquinone.

(d) Vitamin B₆ shall be present at a level of at least 15 micrograms of vitamin B₆ for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than

that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

[50 FR 45108, Oct. 30, 1985]

Subpart E—Infant Formula Recalls

SOURCE: 54 FR 4008, Jan. 27, 1989, unless otherwise noted.

§ 107.200 Food and Drug Administration-required recall.

When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

§ 107.210 Firm-initiated product removals.

(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to § 107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.

(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in § 7.3(j) of this chapter. As required by § 107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.